

Furthermore, the Examiner states that the description for this expression is limited to the compounds at page 4, lines 12-14 of the specification. The Applicant respectfully disagrees that the language is limited to those compounds. One of ordinary skill in the art will readily comprehend exactly what compounds are metabolized to nicotinic acid in the body. This is a readily verifiable and ascertainable characteristic of a compound. Therefore, the Applicant believes that the language as filed is adequate. However, in the spirit of compact prosecution, claim 1 has been amended to remove the language. Further, new claim 13 has been added hereto in order to recite four of the compounds for which the Examiner states there is adequate description in the specification. Therefore, the Applicant believes that the objection to the specification and to claims 1-9 and 11 is overcome.

Also under 35 U.S.C. § 112, the Examiner has rejected claims 5, 7 and 10-12. In claim 5, the incorrect usage of the percent symbol (%) has been deleted in favor of the language "parts by weight" which appeared in the claim originally. No new matter has been added, and the Applicant believes that it is evident from the specification and claims as filed that parts by weight are used in this application. The Examiner's attention is respectfully drawn to claims 6 and 8 as examples of parts by weight. Furthermore, claim 5 recites an amount of a compound based upon 100 parts by weight of a tablet. Therefore, again, it is evident that parts by weight were intended, and the use of the percent symbol (%) was inadvertent.

The suggestion made by the Examiner as to claim 1 has been adopted. Finally, under 35 U.S.C. § 112, the Examiner has requested that structures for the compounds of claim 10 and 12 be provided. The Applicant notes that these compounds are presently being reviewed and structures will be provided as soon as they are available. However, in order to facilitate the prosecution of this case, the Applicant is filing this response in the interim.

Claims 10-12 have been cancelled in view of new claim 13. Therefore, the rejection to claim 11 is moot.

Claims 1-9 stand rejected under 35 U.S.C. § 102(e) as being clearly anticipated by U.S. Patent No. 5,268,181 to O'Neill. The Applicant notes that claims 10-12 have not been rejected based upon any prior art reference. Therefore, because new claim 13 contains the recitations of original claims 1, 10 and 12, the Applicant believes that claim 13 is in condition for allowance.

Turning now to the rejection of claims 1-9, the Applicant has submitted herewith the Declaration Under 37 CFR § 1.131 of David J. Bova, the named inventor in this application. The 1.131 Declaration shows a reduction to practice of the present invention prior to June 29, 1992, which is the filing date of the O'Neill reference. Attached to the 1.131 Declaration are pages from a document entitled "A Single-Blind Placebo Controlled Pilot Study Comparing the Effect of Once-a-Day Versus Twice-a-Day Dosing of Sustained Release Niacin on Serum Lipids". The document has been signed and states that a study to be conducted includes the dosing of niacin once-a-day at night. Furthermore, the indication for the study is specifically stated as the reduction of serum cholesterol. Therefore, the Applicant believes that this document shows a reduction to practice of the present invention prior to the filing date of the O'Neill reference. Furthermore, it is also stated in the Declaration that the reduction to practice was made in the United States. Finally, the Applicant notes that the O'Neill reference claims a very specific compound for reducing serum lipids, which is an admixture of various components. The amounts of each of the components is also stated, as in at least one case, a specific viscosity. The Applicant notes that the present invention as claimed does not recite the specific formulation of the claims of the O'Neill reference. Therefore, the Applicant believes that the claims as presently pending and the claims in the O'Neill reference are directed toward different inventions. All of the requirements of 37 CFR § 1.131 having been met, the Applicant states that the O'Neill reference cannot be a basis for rejecting the present claims.

The Applicant also wishes to explore two points with respect to the 37 CFR § 1.131 Declaration. The first is that while the O'Neill reference is a continuation-in-part of a parent filed in 1989, any mention in O'Neill of a single

dose of nicotinic acid in the evening or at night was added in the continuation-in-part filed June 29, 1992. Prior to that, the Applicant believes that there is no disclosure as to once-a-day dosing at night. The Applicant has obtained the file history of the O'Neill reference and have reviewed it thoroughly and believe this to be the case. If the Examiner would care to review this matter, the Examiner is respectfully invited to obtain the file history of the O'Neill reference. In the spirit of compact prosecution, the Applicant would also be willing to provide his copy of the O'Neill file history to the Examiner, if requested.


Finally, with respect to the Declaration, and in a somewhat opposite manner to the O'Neill reference, the Applicant notes that his disclosure of once-a-day dosing at night was made in the original parent application to the present patent application, which parent was U.S. Patent Application Serial No. 08/124,392 filed in September of 1993. The O'Neill reference issued in December of 1993. Therefore, under 37 CFR § 1.131, the O'Neill reference did not exist as a printed patent more than one year before the filing date of the present application. Therefore, again, the dictates of § 1.131 have been met and O'Neill is effectively removed as a basis for rejection of the present claims.

The Applicant believes that with the foregoing amendments to the claims, in view of the explanations provided in the remarks hereinabove, that the present claims are in condition for allowance. Therefore, the Examiner is respectfully requested to enter the foregoing amendments to the specification and claims and to reconsider the instant application in view of the amendments and remarks made hereinabove. A formal Notice of Allowance of claims 1-9 and 13 is earnestly solicited.

Following the amendments herein, the total number of claims remains 20 or less and the total number of independent claims remains 3 or less. Therefore, the Applicant believes that no new fees are due at this time.

Should the Examiner care to discuss any of the foregoing in greater detail, the undersigned attorney would welcome a telephone call.

Respectfully submitted,

  
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